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H. L. King

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PATENT  
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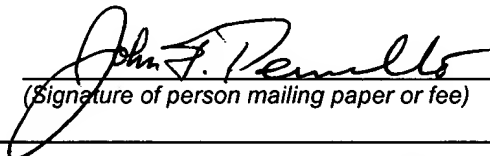
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Richard A. Gambale et al.  
Serial No.: 09/774,320  
Filed: January 31, 2001  
For: VASCULAR INDUCING IMPLANTS  
Examiner: Sharon E. Kennedy  
Art Unit: 3763

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Commissioner for Patents  
Washington, DC 20231

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AMENDMENT

TECHNOLOGY CENTER R3700

Sir:

In response to the office action dated July 19, 2002, please amend the above-entitled application as follows:

In the Claims

Please amend claim 3 as follows:

3. (Amended) An agent delivery system as defined in claim 2 wherein the body has proximal and distal portions and coils along the proximal portion define a second inside diameter that does not accept the pellet.

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Please amend claim 4 as follows:

4. (Amended) An agent delivery system as defined in claim 2 wherein the coils at the distal portion of the body further define a diameter that does not accept the pellet.

Please amend claim 5 as follows:

5. (Amended) An agent delivery system comprising:
- a pellet containing a therapeutic agent;
  - a flexible and implantable body defining an interior sized to accept the pellet and proximal and distal ends. The proximal end being sized to accept the pellet and at least one opening sized to permit bodily fluid to enter the interior of the device but to prevent the pellet from exiting the interior of the device;
  - an implant delivery device;
  - a pellet delivery tube engagable with the proximal end of the body.

Please amend claim 10 as follows:

10. (Amended) An agent delivery system comprising:
- a pellet containing a therapeutic agent;
  - a flexible, implantable body having an interior configured to receive the pellet and retain it after the implant has been placed in tissue;
  - an obturator configured to pierce tissue;
  - an insertion device configured to retain the pellet within the interior of the implant device for simultaneous delivery into an intended tissue location.

### REMARKS

This amendment is in response to the office action dated July 19, 2002. A petition for a two month extension of time and appropriate fee accompany the amendment. Additionally, an information disclosure statement and PTO 1449 form, including all references, are also filed herewith.

### Claim Amendments

Several of the claims have been amended to correct typographical or clerical errors that were present in the application as filed. Claims 3 and 4 have been amended to add the word "system" to the preamble of the claim to be consistent with the base

claim 1. Claim 5 has been amended in line 2 to change the word "substance" to "agent" to maintain consistency with the preamble of the claim as well as with the language of the other claims. In line 3 of claim 5, a typographical error has been corrected changing "plantable" to "implantable". Claim 10 has been amended at line 2 to change "substance" to "agent" for the same reasons discussed above in connection with claim 5. Also at claim 10, line 3, a typographical error has been corrected changing "configure" to "configured". The several amendments have been made solely to correct clerical errors and should not be considered to impact the scope of the claims.

#### **Claim Rejections Under 35 U.S.C. §102**

##### **The Rejection of Claims 1-11 as Anticipated by U.S. 5,891,108 (Leone et al.)**

In the action, claims 1-11 were rejected as anticipated by Leone et al. The Leone patent is directed to an expandable tubular stent formed from hollow wire having multiple perfusion ports formed therein. When placed in position in a vessel, the proximal end of the stent remains connected to a liquid drug delivery system. Liquid drugs are injected through the delivery system into the tubular wire of the stent and exude through the perfusion ports to reach the surrounding vessel tissue.

Nowhere in the Leone patent is a pellet containing a therapeutic agent disclosed nor is an implant with a hollow interior configured to receive such a pellet disclosed. Each of applicants' claims contains those limitations. In order to be anticipated, each and every claim limitation must be disclosed in a single reference. Because the Leone patent fails to disclose or suggest several of the limitations of applicants' claims, it cannot be considered to anticipate those claims. Accordingly, claims 1-11 should be considered to be patentable over Leone et al.

##### **Rejection of claims 1-11 as Anticipated by U.S. 6,019,779 (Thorud)**

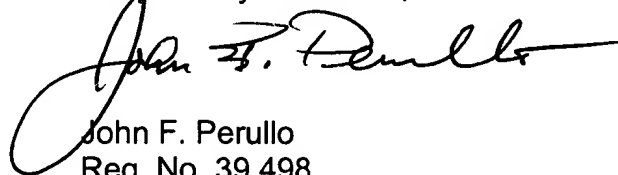
The Thorud patent is directed to a multi-filar coil stent. The stent is formed from multiple wire elements coiled together in a side-by-side or overlapping fashion. The

proximal and distal ends of the multiple coil wire elements are joined together to form an enlarged ball tip at each end of the stent. The ball tip purportedly facilitates delivery of the stent on the exterior of a catheter by providing a location over which a suture braid may be used to secure the coiled stent in a low profile form over the catheter. Additionally, the ball tip end provides a grasping point for a stent retrieval tool. The patent states that the stent may be coated with metals, drugs, polymers or radioactive compounds.

Nowhere in the Thorud et al. specification is a pellet containing a therapeutic agent disclosed. The patent also fails to disclose an implant configured to receive such a pellet within its interior. As discussed above in connection with the rejections based on the Leone patent, a reference must disclose each and every element of a claim in order to anticipate that claim. Because the Thorud patent fails to disclose several elements of each of applicants' claims, it cannot be considered to anticipate those claims.

Accordingly, because neither the Leone or Thorud references disclose each and every element of applicants' claims, neither reference should be considered to anticipate those claims. Claims 1-11 thus should be considered to be patentable and in condition for allowance.

Respectfully submitted,



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